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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,783	09/23/2003	Miroslav Smriga	241244US0CONT	9560

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
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ALEXANDRIA, VA 22314

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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09/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/667,783	Applicant(s) SMRIGA ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14-23 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed July 20, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites "lysine is in a salt form salt". The claim is not further limiting because the lysine has already been described as a salt in the independent claim.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 14-23 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The claims recite "wherein the lysine is in a salt form salt with glutamic acid". It is not clear from the instant claims or the instant specification if the lysine is complexed with glutamic acid or if lysine is a free salt and glutamic acid is present in the composition. Especially considering claim 3 recites lysine is in a free form and claim 4 recites lysine is in a salt form, thus making the claims indefinite.

2) Claim 3 recites "lysine is in a free form". The claim is indefinite insofar as lysine has been described to be in salt form in the independent claim. There is confusion as to whether lysine is in free form or in salt form therefore making the claim indefinite.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 1-4, 6-10, 12, 14-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagi et al. (US 3,988,466). The rejection is maintained in regards to claims 1-4, 6-10, 14-23 and 30-32. Claim 12 is cancelled.

Applicant's Arguments

Applicant has amended the claims to add subject matter recited in claim 12. Applicant argues there is not disclosure that lysine is in a salt form with glutamic acid and/or that the composition comprises arginine. Further the gastric lesions disclosed therein do not have anything to do with stress. The reference also fails to disclose that the subject to be treated has been diagnosed with or have a recognized need to treat the recited disorder or to bring about the recited effect. Preventing as disclosed by the reference is incompatible with "ameliorating, progress blocking, or therapeutically treating" as recited in the instant claims. The fact that something has a preventative effect has absolutely no predictive value as to its ability to treat the thing that it should to prevent. This argument is not persuasive.

Examiner's Response

In regard to the lysine not being in salt form, the reference discloses lysine hydrochloride, which is lysine in salt form. When glutamic acid is used in conjunction with lysine in its salt form, it encompasses the limitation "lysine is in a salt form salt with glutamic acid" (see indefiniteness rejection above). Upon further consideration, drugs may be stressors and therefore a condition caused by these drugs would be considered stress-induced. Therefore the conditions disclosed by the reference may be considered stress-induced. The reference discloses that not all of the amino acids have the same

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effectiveness, which leads one to conclude that lesions did develop and therefore the subject has been diagnosed with the condition. This would also encompass “progress blocking or therapeutically treating”, because the amino acids inhibited the full development of the gastric lesions. Further the reference discloses that amino acids have been reported to be effective for the treatment of experimental ulcers such as those induced by stress or chemically (col. 1, lines 25-30). Therefore based on the reference, it would have been obvious to use these amino acids not only to prevent the lesions but to also treat the lesions. It would also have been obvious to treat stressed-induced lesions.

Additionally, In KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, “obviousness to try” such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to treat stress induced lesions. Accordingly, it would have been obvious to have used the amino acids disclosed to prevent lesions and have been reported to treat ulcers induced by artificial stress and chemicals to treat the stress-induced condition of gastric ulcers of the instant claims.

2) Claims 1-4, 6-10, 12, 15-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niebes et al. (US 4,507,314) in view of Takagi et al. (US

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3,988,466). The rejection is maintained in regards to claims 1-4, 6-10, 15-23 and 30-32.

Claim 12 is cancelled.

Applicant's Arguments

Applicant argues Niebes et al. does not disclose or suggest lysine in salt form with glutamic acid and that the composition further contains arginine. Further Applicant has implied unexpected results when lysine glutamate is used or lysine in combination is used with arginine. This argument is not persuasive.

Examiner's Response

Although Niebes does not disclose a salt specifically, it does disclose catechin hydrochlorolysinate, which encompasses a lysine in salt form. Further the claims recite a lysine is L-lysine which encompasses other forms besides a salt. Takagi et al. disclose glutamic acid and provides motivation as to why one of ordinary skill in the art would want to combine the lysine of the Niebes with the glutamic acid of Takagi et al.

In regard to Figure 6, more amino acid is used when a combination is administered and therefore one would reasonably expect an increase in efficacy. In regard to Figure 7, the results cannot be independently evaluated because there are no examples that show the results of a glutamate salt or arginine and therefore a proper comparison cannot be made. The amino acids may have different efficacies. These efficacies will affect the results. For instance, if arginine is more efficacious than lysine, it will take less arginine to obtain the same results as lysine and therefore when the two are mixed, it is reasonable to conclude that the same amount of lysine and arginine will

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yield better results than lysine alone because arginine is more effective. In regard to Figure 8, it appears the feeding at normal density is about the same for lysine and the lysine/arginine combination. Additionally a proper comparison cannot be made because there are not results with arginine alone. As stated above the amino acids may have different efficacies which would affect the results.

3) Claims 1-10, 12, 14-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krnjevic (US 4,405,610) in view of Takagi et al. (US 3,988,466). The rejection is maintained in regards to claims 1-10, 14-23 and 30-32. Claim 12 is cancelled.

Applicant's Arguments

Applicant argues Krnjevic does not disclose or suggest lysine in salt form with glutamic acid and that the composition further contains arginine. Further Applicant has implied unexpected results when lysine glutamate is used or lysine in combination is used with arginine. This argument is not persuasive.

Examiner's Response

Krnjevic discloses a lysine salt and Takagi et al disclose glutamate and arginine are therapeutically effective against gastric ulcers. Thus it would have been obvious to use a combination of the three to treat gastric ulcers. As stated above, the recitation of "lysine is in a salt form salt with glutamic acid" is indefinite and may be interpreted to encompass a lysine salt and glutamic acid, thus the combination encompasses the

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instant claims. See Examiner's Response above in regard to Applicant's asserted results.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1-10, 14-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krnjevic (US 4,405,610) in view of Rath et al. (US 5,650,418) and Takagi et al. (US 3,988,466).

Krnjevic disclose compositions for treating conditions such as gastric ulcers with compositions comprising lysine orotate (col. 1, lines 19-26). The drug was given to patients in a dose of 25 mg a day and was usually administered in tea or undiluted milk. When in liquid form, 1.5 ml of composition with a concentration of 3 mg/ml (0.3%) is administered per 0.25 kg of body weight (18 mg per kg per body) (see claim 1). The reference differs from the instant claims insofar as it does not disclose the composition comprises arginine or lysine-glutamate.

Rath et al. disclose therapeutic lysine salts. The active agent is lysine yet its salts may be used in place of lysine. These salts include lysine hydrochloride, lysine dihydrochloride, lysine orotate and lysine glutamate. The reference differs from the instant claims insofar as it does not disclose the salts are used to treat stress induced conditions.

Takagi et al. is disclosed above. Takagi et al. disclose that glutamic acid and arginine are used for therapeutic treatment to block the progress of gastric ulcers. The

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reference differs from the instant claims insofar as it does not disclose the ulcers are stress induced.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See MPEP 2144.06. It would have been obvious to one of ordinary skill in the art to have used lysine glutamate in place of lysine orotate as the lysine in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

It is also prima facie obviousness to select a known material based on its suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have added glutamic acid and arginine to the compositions of the primary reference motivated by the desire to use components that have been disclosed in the art as being effective in blocking the progress gastric ulcers. It would also have been obvious to use lysine glutamate in the compositions of Krnjevic motivated by the desire to use a therapeutic lysine salt comprising two amino acids reported to have a therapeutic effect on gastric ulcers, as supported by Rath et al. and Takagi et al.

Claims 1-10, 14-23 and 30-32 are rejected.

Claims 24-26 and 28-29 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612